

REMARKS

Claims 1-9, 11-15, 21, 27, and 32 are pending after entry of this paper. Claims 1-15, 20, 21, 27 and 32 have been rejected. Claims 10, 16-20, 22-26, 28-31 and 33 have been cancelled without prejudice. Applicants reserve the right to pursue cancelled claims in a divisional or continuing application.

Claims 1, 9, 13-15, and 20 have been amended. Support may be found throughout the instant specification.

Claim 1 has been amended, i) to include the phrases “molecule comprising a nucleotide sequence,” “(c) a nucleic acid sequence comprising at least 289 consecutive nucleotides of SEQ ID NO. 2 or SEQ ID NO. 4,” and “(e) a complement of (c) or (d),” ii) to remove references to sequences which were not elected in this application, iii) to amend the phrase “complementary nucleic acid sequence” to “a complement of,” and iv) to replace “50” with “500 consecutive.” Support for these amendments is described in detail below.

Claim 9 has been amended i) to delete the phrase “50 consecutive nucleotides of,”; ii) to include the phrases: “289 consecutive nucleotides of,”; “500 consecutive nucleotides of,”; and “(c) a complement of (a) or (b),”; and iii) to amend the syntax for clarity. Support for these amendments is described in detail below.

Claim 13, 14, and 15 have been amended to depend from claims 12, 13, and 12, respectively. Support for these amendments is described in detail below.

Claim 21 has been amended i) to replace “variant of” with “polynucleotide comprising the sequence of”, ii) to remove reference to SEQ ID NOs 2, 6, 8, and 10, and iii) to replace “wherein the variation contains one or more SNPs from Table 5” with “wherein position

1389 has a cytosine to thymine substitution.” Support for these amendments is described in detail below.

Claim 27 has been amended to replace “15” with “289” and to replace “BAC RP11-0702C13 of” with “the nucleotide sequence.” Support for this amendment is described below.

The syntax of claim 32 has been amended for clarity.

No new matter has been introduced by these amendments, support for these amendments is described in detail below. Reconsideration and withdrawal of the pending rejections in view of the above-mentioned claim amendments and below remarks is respectfully requested.

Response to Elections/Restrictions

Applicants acknowledge that the Examiner has rejoined SEQ IDs No. 1, 2, 6, 8, and 10 to be examined with SEQ ID NOs. 4 and 49 in this application.

Response to Claim Interpretation

Applicants acknowledge that the Examiner has withdrawn the rejection to Claim 27 for being anticipated by the BACPAC filters.

Response to Claim Objections

Claims 13-15 have been objected to for being identical to claims 6-8. Applicants have amended claims 13, 14, and 15 to depend from claims 12, 13, and 12, respectively. Support can be found throughout the instant specification and claims as filed, for example, page 19, lines 15-16. Applicants believe that this amendment addresses the Examiner’s concerns.

The Examiner has objected to claims 20-21 for containing references to sequences and SNP sites described in tables. Claim 20 has been cancelled and claim 21 has been amended to specifically refer to an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO. 4 wherein position 1389 has a cytosine to thymine substitution. These amendments do not contain new matter and are fully supported throughout the instant specification and claims as filed, for example on page 65 in Table 5. Applicants believe that these amendments obviate the Examiner's objections.

Applicants respectfully request reconsideration and withdrawal of the claim objections in view of the above-mentioned amendments.

Response to Rejections under 35 U.S.C. §112, second paragraph

Claim 21 has been rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner contends that claim 21 is “indefinite over the recitation ‘an isolated variant of SEQ ID No. 4.’” The Examiner further contends that it is not clear what limits the claim with regard to the polymorphisms and that it is not clear what it means for a nucleic acid to “contain” a polymorphism (Office Action – Page 5). Applicants disagree with the Examiner's contentions.

However, in order to expedite prosecution and solely for the purpose of allowance of the instant application, applicants have amended claim 21 to include the position and type of substitution/polymorphism per the Examiner's suggestion. Claim 21 now reads (emphasis added), “An isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO. 4

wherein position 1389 has a cytosine to thymine substitution.” Support for this amendment can be found throughout the instant specification and claims as originally filed, for example on page 65 in Table 5 and the Sequence Listing. Applicants believe that this amendment addresses the Examiner’s concerns. Therefore, applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Response to Rejections under 35 U.S.C. §112, first paragraph

Claims 1-15, 20-21, 27 and 32 stand rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. While the Examiner acknowledges that “nucleic acids consisting of SEQ ID NO. 2, 4, 6, 8, or 10 meet the written description requirements” (Office Action – Page 6), the Examiner contends that “it is noted that “a complementary nucleic acid sequence” is being broadly interpreted as encompassing any fragment of SEQ ID NO. 2, 4, 6, 8, or 10 and not the full length sequences” (Office Action – Pages 6).

Applicants respectfully disagree with the Examiner’s contention. However, in order to expedite prosecution and solely for the purpose of allowance of the instant application, applicants have amended independent claims 1 and 9. Applicants assert that amending the phrase “a complementary nucleic acid sequence of” to “a complement of” clearly and sufficiently describes to one skilled in the art that the claims encompass the complement of the full length sequences or at least 289 or 500 consecutive nucleotides thereof. No new matter has been introduced with these amendments. Support can be found throughout the instant specification and claims as filed, for example, page 11, lines 10-17. Applicants believe that this amendment addresses the Examiner’s concerns with regard to this point.

The Examiner further contends that, “the claims as broadly written encompass flanking sequences [of] unspecified length” (Office Action – Page 6 and 7) and “isolated nucleic acids comprising fragments of SEQ ID NO. 1, 2, 4, 6, 8, or 10 without any description of the nucleotides flanking the fragments.” Applicants respectfully disagree with the Examiner’s contention.

The amended claims are directed to nucleic acid sequences comprising consecutive nucleotides of SEQ ID NO. 1, 2, 4, 6, 8, 10, and 49. Applicants assert that there is a sufficient written description of the nucleotides flanking the fragments, as these flanking sequences have been described in the instant specification and claims as being fragments, or a “portion,” of the full-length sequences described in the sequence listings. Support can be found, for example, at page 5, lines 6-12 and page 11, lines 10-17. Applicants assert that the instant invention is adequately described within the specification, claims and defined sequence listing of the instant application. The Examiner’s contention that a description of the nucleotides flanking the fragments is moot for the above reasons.

The Examiner also contends that “the claims as broadly written encompass the specification does not provide an adequate written description of the claimed genus of nucleic acids as the claims are broadly written” (Office Action – Page 7) Applicants respectfully disagree with this rejection.

However, in order to expedite prosecution and solely for the purpose of allowance of the instant application, applicants have amended independent claims 1, 9, and 21. Claims 1 and 9 have been amended to describe the **full-length sequences** and their corresponding

complements; and **fragments** of full-length sequences and their corresponding **complements** (emphasis added). Claim 21 has been amended to describe SEQ ID NO. 4 and particular positions within this sequence. No new matter has been introduced with these amendments. Support can be found throughout the instant specification, claims, and sequence listing as filed. For example, page 5, lines 6-21 and page 11, lines 18-30 for claim 1; page 11, lines 18-30 for claim 9; and page 65, Table 5 for claim 21.

Applicants assert that the above-mentioned amendments to the claims provide sufficient description of the invention and as claimed herein allow one skilled in the art to recognize that the applicants were in possession at the time of filing of the invention. The amended claims are specifically directed to the sequences and substitution of the invention. Therefore, the applicants assert that the amended claims provide an adequate written description of the claimed genus of nucleic acids, namely the sequences as referenced by the sequence identifiers.

The Examiner also contends that “the specification allegedly fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids in view of the species disclosed” (Office Action – Page 8). However, the applicants believe that the above-mentioned amendments render this point moot (*i.e.*, the species in the amended claims must comprise consecutive nucleic acids of the defined sequences of SEQ ID NO. 1, 2, 4, 6, 8, or 10).

The Examiner further contends that “the variants [of SEQ ID NO. 1, 2, 4, 6, 8, or 10] may include nucleotide substitutions, additions, deletions, translocations and truncations...” (Office Action – Page 7). Applicants disagree with the Examiner’s contention. However, in order to expedite prosecution and solely for the purpose of allowance of the instant application,

applicants have amended claim 21 to be directed to a specific nucleotide and polymorphism of SEQ ID NO. 4. Applicants believe that the amendment to claim 21 addresses the Examiner's concerns to this point.

Applicants assert that the amended claims comply with the written description in view of the aforementioned amendments and arguments. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, written description.

Response to Rejections under 35 U.S.C. §102

Claims 1-5, 9-12, 15, 20-21, 27 and 32 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shankar, et al. (*Biochem. J.* 1994 Vol 300 p. 295) as evidenced by GenBank Accession Number U14383 (NCBI website December 31, 1994). Specifically, the Examiner has rejected claims 1 and 9, because "GenBank Accession No. U14383 teaches a sequence which is 87.7% similar over the entire length to SEQ ID NO. 4 (Office Action – Page 10). Applicants disagree this rejection.

However, in order to expedite prosecution and solely for the purpose of allowance of the instant application, applicants have amended claim 1 such that it is directed to the **full-length sequences**; the **complements** of the full-length sequences; at least **289** consecutive nucleotides of SEQ ID NO. 2 or 4; **500** consecutive nucleotides of SEQ ID NOs. 6, 8, or 10; or the **complements** of the fragments (emphasis added). Claim 9 has been amended and is directed to a DNA or RNA of at least **289** consecutive nucleotides of SEQ ID NOs. 2 or 4; **500** consecutive nucleotides of SEQ ID NOs. 6, 8, or 10; or the **complements** of the fragments

(emphasis added). Support for a sequence of 289 consecutive nucleotides is in SEQ ID NO. 39, and for a sequence of 500 consecutive nucleotides on page 5, lines 6-12. Furthermore, claim 1 has been amended to replace the phrase “which hybridizes under stringent conditions” with “complement of.” Support can be found throughout the instant specification and claims as originally filed, for example, page 11, lines 10-17.

As stated in MPEP §2131, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” As Shankar, et al. and GenBank Accession No. U14383 do not teach each and every element of amended claim 1 or 9, Shankar, et al. and GenBank Accession No. U14383 do not anticipate the claims. In fact, Shankar and the GenBank Accession No. U14383 disclose a sequence that is **87.7%** identical to SEQ ID NO.4 of the instant invention (emphasis added). In order for GenBank Accession No. U14383 to be anticipatory, its sequence must be 100% identical to SEQ ID NO:4. Furthermore, with respect to claims 1 and 9, the sequence disclosed under GenBank Accession No. U14383 does not contain 289 consecutive nucleotides which are identical to a sequence of SEQ ID NO. 2 or 4 in the claimed invention, nor does the U14383 sequence contain 500 consecutive nucleotides which are identical to a sequence of SEQ ID NO. 6, 8, or 10 in the claimed invention. Additionally, Shankar, et al. and GenBank Accession No. U14383 do not anticipate the other elements of claim 1. As claims 2-5, 8, 11, 12, 15 and 32 depend from either claim 1 or 9, applicants assert that these claims are also not anticipated by Shankar, et al. and GenBank Accession No. U14383 because, as discussed in detail above, the cited references do not disclose each and every element of the claim. Applicants have cancelled claim 10 without prejudice, which renders the rejection to this claim moot. Applicants

respectfully request reconsideration and withdrawal of the 35 U.S.C. §102(b) rejection to claims 1-5, 8, 9, 11, 12, 15 and 32 in view of the above-mentioned amendments and arguments.

With regard to Claim 20, the Examiner contends that “GenBank Accession No. U14383 comprises a polynucleotide, which has at least 15 consecutive nucleotides of any of the nucleic acids of Table 5 (SEQ 49) wherein there is a SNP site.” Applicants have cancelled claim 20 thereby rendering this rejection moot.

With regard to claim 21, the Examiner contends that U14383 comprises a sequence that is **89.5%** identical to SEQ ID NO. 4; therefore, U14383 is a variant of SEQ ID NO. 4. Applicants respectfully disagree with the Examiner’s contention. Applicants have amended claim 21 to specifically indicate the position and polymorphism of SEQ ID NO 4. However, regardless of the position of the SNP, applicants direct the Examiner’s attention to the base sequence prior to the position 1389 of SEQ ID NO.4. The cited reference has a deletion of a guanine base compared to the instant sequences, which has been noted by the Examiner on page 11 of the Office Action. Applicants assert that the claimed subject matter is not disclosed by the Genbank sequence and, therefore, does not anticipate the cited sequence.

With regard to claim 27, the Examiner contends that “U14383 comprises at least 15 nucleotides of SEQ ID NO. 1.” Applicants disagree with the Examiner’s contention, however, applicants have amended claim 27 in order to expedite prosecution and solely for the purpose of allowance of the instant application. Claim 27 is directed to a fragment comprising at least 289 consecutive nucleotides of the nucleotide sequence SEQ ID NO. 1. No new matter has been introduced by this amendment and support can be found throughout the instant

specification and claims, specifically in SEQ ID NO. 39 in the sequence listing. As Shankar, et al. and GenBank Accession No. U14383 do not teach each and every element of amended claim 27, Shankar, et al. and GenBank Accession No. U14383 do not anticipate the claim.

Specifically, GenBank Accession No. U14383 does not disclose 289 consecutive nucleotides which are identical to 289 consecutive nucleotides of SEQ ID NO: 1 in the claimed invention.

With regard to claim 32, the Examiner contends that Shankar, et al. anticipate the claim because Shankar “teaches probes and hybridization reagents (random primer labeling kit). Applicants respectfully disagree with this rejection. Claim 32 depends from amended claim 1, which is not anticipated by Shankar, et al. Furthermore, the Examiner contends that claim 32 has not been given patentable weight because the recitation of ‘detecting chromosome 12 disorder in a biological sample’ occurs in the preamble (Office Action – page 11). Applicants respectfully disagree with the Examiner’s contention. However, in order to expedite prosecution and solely for the purpose of allowance of the instant application, applicants have amended the syntax of Claim 32, for clarity. No new matter has been introduced by this amendment. Applicants believe that this amendment addresses the Examiner’s concerns regarding this point.

Applicants believe that the amended claims are not anticipated by Shankar, et al. as evidenced by GenBank Accession No. U14383, in view of the above-mentioned claim amendments and arguments. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Response to Rejections under 35 U.S.C. §103

Claims 6-7 and 13-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Shankar, et al. (*Biochem. J.* 1994 Vol 300 p. 295) as evidenced by GenBank Accession Number U14383 (NCBI website December 31, 1994) in view of Laskey, et al. (U.S. Patent No. 5,304,640 April 19, 1994). Specifically, the Examiner contends that “it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have transformed human host cells with vectors comprising the nucleic acid taught by Shankar, et al.” Applicants respectfully disagree with the Examiner’s rejection.

As indicated previously, claims 1 and 9 have been amended to contain sequences which have not been taught by Shankar, et al. The Examiner has combined Shankar with Laskey, et al. (USPN: 5,304,640) for teaching human (eukaryotic) host cells which admittedly is not taught by Shankar. However, regardless of whether Laskey teaches the use of human host cells and what the Examiner claims was routine in the art regarding the transformation of human host cells with vectors comprising nucleic acids encoding human proteins, the combination of GenBank Accession Number U14383 of Shankar and Laskey does not result in the claimed invention. In fact, Laskey does not remedy the deficiencies of GenBank Accession Number U14383 with respect to the nucleic acid molecule. As the host cells of claims 6-7 and 13-14 are dependant from the isolated nucleic acid molecule of claims 1 and 9, respectively, applicants assert that the amendments to claims 1 and 9 obviate this ground of rejection. Therefore, applicants respectfully request reconsideration and withdrawal of rejections under 35 U.S.C. §103 (a).

Response to the issue of Double Patenting

Claims 1-15 and 27 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, and 13-25 of U.S. Patent No. 6,737,519. Applicants respectfully disagree. However, in order to expedite prosecution of the instant application and solely for the purpose of allowance, applicants submit herewith an executed Terminal Disclaimer. Reconsideration and withdrawal of the Double Patenting rejection are respectfully requested.

DEPENDENT CLAIMS

The applicants have not independently addressed all of the rejections of the dependent claims. The applicants submit that for at least similar reasons as to why independent claims 1, 9, 20 and 21 from which all of the dependent claims 2-8, 10-19, and 22-32 depend are believed allowable as discussed *supra*, the dependent claims are also allowable. The applicants however, reserve the right to address any individual rejections of the dependent claims and present independent bases for allowance for the dependent claims should such be necessary or appropriate.

Thus, applicants respectfully submit that the invention as recited in the claims as presented herein is allowable over the art of record, and respectfully request that the respective rejections be withdrawn.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

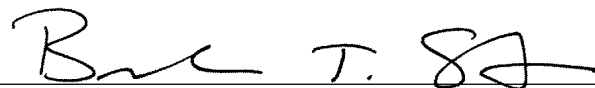
The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 2976-4037US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 2976-4037US1.

Respectfully submitted,
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